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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/010,310 | 11/13/2001 | Elias Georges | 112418.122 | 5815 |

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| EXAMINER | |
|---|---|
| GABEL, GAILENE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/010,310 | GEORGES, ELIAS | |
| | Examiner | Art Unit | |
| | Gailene R. Gabel | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *42-50,52,55,56,58-69 and 72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, 40, are 75-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Amendment Entry*

1. Applicant's amendment filed 12/17/04 is acknowledged and has been entered. Claims 10, 12-17, 19, 26, 27, 29-34, 42, 45-50, 58, and 60-67 have been amended. Claims 1-9, 18, 21, 22, 25, 28, 35, 37, 38, 41, 51, 53, 54, 57, 70, 71, 73, and 74 have been cancelled. Claims 75-78 have been added. Accordingly, claims 10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, 40, 42-50, 52, 55, 56, 58-69, 72, and 75-78 are pending.

### *Election/Restrictions*

2. In regard to the restriction requirement mailed to Applicant on 12/8/04, Applicant provisionally elected Group Ii, claims 10-20, 22, and 23, with traverse. The traversal included a request for rejoinder of Group Iii, IIi, and IIii with Group Ii.

3. In light of Applicant's amendment of the pending claims, cancellation of selected claims, addition of new claims, and as discussed during the telephonic interview with Applicant on 12/13/04, a further restriction requirement is warranted and has been set forth.

The claims are now deemed to encompass three groups of inventions:

I. Claims 10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, 40, and 75-78, drawn to method of identifying polypeptide having specificity for binding a peptide, classified in class 435, subclass 7.92, for example.

II. Claims 42-50, 52, 55, and 56, drawn to method of identifying a compound that modulates binding between polypeptide and a peptide, classified in class 436, subclass 523, for example.

III. Claims 58-69 and 72, drawn to support having attached thereto, overlapping peptides, classified in class 435, subclass 287.2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects in that the set of peptides in Invention I are combined with a polypeptide to identify specific binding therebetween and in Invention II, the set of peptides are combined with a polypeptide in the presence of a test compound to determine its modulatory effect upon their binding interaction.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the support can be used for affinity chromatography to capture and isolate selected protein.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the support can be used in laser trapping method for capturing specific selected protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search required for Group I is not required for Group II and the search for Group II is not required for Group III, restriction for examination purposes as indicated is proper. Literature search for each method and product is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

4. In acknowledgement of Applicant's traversal of the original restriction requirement (12/8/04) and in accordance to Applicant's request for rejoinder of claims 10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, and 40 (inclusive of Groups I and II of the original restriction), Group I is now deemed to include all of claims 10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, and 40. Claims 42-50, 52, 55, 56, 58-69 and 72 (inclusive of Groups III and IV of the original restriction), are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, 40, 42-50, 52, 55, 56,

58-69, 72, and 75-78 are pending. Claims 10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, 40, are 75-78 are under examination.

### *Abstract*

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words.

### *Sequence Compliance*

6. The drawings contain several nucleotide/amino acid sequences which are encompassed by the definitions for nucleotide/amino acid sequences as set forth in 37 C.F.R. 1.821 (a)(1) and (a)(2) and which must conform with the sequence rules for all applications that include nucleotide/amino acid sequences. The sequence identifiers obtained through conformance (paper submission and CRF/electronic) must be inserted into the body of the specification directly following the sequence.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10-17, 19, 20, 23, 24, 26, 27, 29-34, 36, 39, 40, and 75-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any literal support for the recitation of "wherein the polypeptide is not an antibody". Throughout the specification are discussions of protein-protein interactions, peptide-protein binding, overlapping peptides spanning a complete sequence of a chosen protein incubated and tested for binding or high-affinity interaction with a mixture of proteins or peptides, polypeptides being referred to as linear stretch or sequence of the amino acids which include any one of but not limited to mutants, homologs, or subtypes, but nowhere in the specification provides literal or descriptive support for the recitation of "wherein the polypeptide is not an antibody". This rejection is based on lack of written description for the recitation of a negative limitation excluding antibodies from the scope encompassing polypeptides, but not supported by the specification since specific guidance for the exclusion of antibodies is not taught nor does it flow from the teaching in the specification. Additionally, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal or descriptive support in the specification or originally filed claims constitutes new matter. See In re ANDERSON, 176 USPQ 331 (CCPA 1973).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10-16, 19, 23, 26, 27, 29-33, 39, and 75-78 are rejected under 35 U.S.C. 102(b) as being anticipate by Miwa (EP 0 818467 A2).

Miwa discloses a method for identifying binding or interaction between peptides from a chosen protein and a polypeptide. Miwa teaches covalently attaching a set of overlapping peptide segments spanning a complete sequence of a domain of the protein to a support, then incubating the support with a mixture of polypeptide ligands to allow binding of the peptides with the polypeptides from the mixture. The overlapping peptides (aligned peptide array) are synthetically synthesized from the amino acid sequence of the chosen protein. The ligands as taught by Miwa are any one of antibodies, polypeptides (pheromones, hormones), and nucleic acids (DNA, RNA). See Abstract; page 2, lines 5-21 and 31-54; page 3, lines 17-28 and 42-57; and page 4, lines 33-41. Miwa teaches that the peptide segments may extend to 10 amino acids in length (see page 3, lines 48-51). The support is washed to remove unbound polypeptides, and the polypeptides bound to the peptides on the support are identified. The support for immobilizing the overlapping peptides may be any one of a microchip or microtiter well plate (see page 4, lines 14-22). The peptide to which the polypeptide binds can be identified by its position on the support, i.e. membrane filter, and observed by microscope or naked (see page 3, lines 36-38 and page 4, lines 14-15) or by labeling

the polypeptide and identifying the labeled polypeptide using assay methods and detection devices (see page 4, line 40-41). In practice at Example 1, Miwa detects for the binding site of tubulin using anti-tubulin antibody.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 10-17, 23, 26, 27, 29-34, 39, and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geysen (US 5,595,915) in view of Miwa (EP 0818467 A2).

Geysen discloses a method for identifying binding or interaction, i.e. antigenically active, between peptides from a chosen (known or selected) protein and a polypeptide (antibody) (see Abstract and Figure 1). Geysen teaches synthetically synthesizing a plurality of peptides from the chosen protein, and covalently attaching a set of peptide segments to a support. The set of peptide segments overlap in parallel, in amino acid sequences and span a complete sequence of a domain of the protein (see column 1, lines 28-57, column 2, lines 49-64, column 3, lines 5-20, and claim 8). The aligned and overlapping peptides are then incubated with antibodies to allow binding of the peptides with the antibodies. The support is washed to remove unbound antibodies and binding between the peptides and antibodies retained on the support is detected and identified

(see column 1, lines 29-61 and column 5, lines 20-23 and 55-59). Geysen specifically teaches that the method can ascertain a high degree of specificity of a polypeptide to identify a specific peptide segment or amino acid sequence (see column 1, line 62 to column 2, line 2). Geysen teaches that the peptide segment range is preferably between 6-8 amino acids in length (see column 2, lines 12-24). The support for immobilizing the overlapping peptides may be any one of solid polymer rod or microtiter well plate (see column 3, lines 5-30). The peptide to which the polypeptide binds can be identified by labeling the polypeptide and identifying the labeled polypeptide using assay methods, i.e. ELISA, RIA, and detection devices (see column 3, line 31-35).

Geysen differs from the instant invention in failing to teach that the polypeptide that binds to a peptide in the chosen protein is not an antibody. Geysen also does not teach using tubulin as polypeptide for the instant method.

Miwa is discussed supra.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute other polypeptide ligands (tubulin) such as taught by Miwa, for the antibodies taught by Geysen for binding peptides in protein interaction methods because Miwa specifically taught that different ligands including antibodies, pheromones, hormones, proteins, nucleic acids, carbohydrates, and lipids can be used for application in his protein binding interactions method; hence, other polypeptides [than antibodies] such as pheromones, hormones, proteins, nucleic acids, carbohydrates, and lipids appear to constitute obvious variation of binding ligands which are routinely varied in the art.

10. Claims 10-17, 20, 24, 26, 27, 29-34, 36, 40, and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georges et al. (Topology of P-glycoprotein as Determined by Epitope Mapping of MRK-16 Monoclonal Antibody, The Journal of Biological Chemistry 268 (3): 1792-1798 (1993)) in view of Miwa (EP 0818467 A2).

Georges teaches identifying a peptide in a chosen protein (human P-glycoprotein 1 or human P-glycoprotein 3) by synthesizing overlapping heptapeptides (7 amino acid length) spanning a complete sequence of a domain of the protein. The peptides are covalently attached to a solid support (plastic pins on a 96-well polypropylene plate). The support is incubated with a mixture of polypeptides (antibodies), washed to remove unbound polypeptides, and detected for binding of the labeled polypeptides with the peptides immobilized on support (ELISA: enzyme label) (see Abstract and page 1793, columns 1-2).

Georges differs from the instant invention in failing to teach that the polypeptide that binds to a peptide in the chosen protein is not an antibody. Georges also does not teach using tubulin as polypeptide for the instant method.

Miwa is discussed supra.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute other polypeptide ligands (tubulin) such as taught by Miwa, for the antibodies taught by Georges for binding peptides in protein interaction methods because Miwa specifically taught that different ligands including antibodies, pheromones, hormones, proteins, nucleic acids, carbohydrates, and lipids can be used

for application in his protein binding interactions method; hence, other polypeptides [than antibodies] such as pheromones, hormones, proteins, nucleic acids, carbohydrates, and lipids appear to constitute obvious variation of binding ligands which are routinely varied in the art.

11. No claims are allowed.

***Drawings***

12. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

BURNS et al. (Journal of Cellular Biochemistry Supp. 17E, pp. 158 (March 1993)) found that RSK sequence in the caboxyterminal region of glycoprotein-88 may be involved with tubulin binding.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 4, 2005

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
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3/4/05